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Regarding "A randomized trial of carotid artery stenting with and without cerebral protection"

Barbato and colleagues[1] are to be congratulated on performing the first randomized trial comparing carotid artery stenting (CAS) with and without the use of a filter-type cerebral protection device. Although their results do not support the common notion that cerebral protection devices reduce the number of embolic events occurring during CAS, several points of concern arise with respect to the conduct of the trial, patient selection and data analysis.

On the basis of a retrospective analysis of non-randomized data with all its inherent limitations, we recently demonstrated that the use of protection devices significantly reduces the incidence of new diffusion-weighted imaging (DWI) lesions after CAS (proportion of patients with any new ipsilateral DWI lesion, 67% in those treated without vs 49% in those treated with protection devices; $P < 0.05$) and that approximately 120 to 140 patients would be needed for a randomized trial on the basis of these data.[2] As already pointed out by the authors, this trial therefore fell far short of a sample size that would be sufficient to detect a significant difference between both treatment modalities. More importantly, subgroup analyses of our data set have indicated that the beneficial effect of protection devices in preventing the occurrence of new DWI lesions might not pertain to older and asymptomatic patients.[3] The negative findings of this trial could thus very well be based on the high number of asymptomatic patients as well as old patients. Along the way it should be noted that a minor or major stroke rate of 13% in asymptomatic patients is unacceptably high, indicating that the majority of patients included in this trial would have been better off with medical treatment alone.

In the past few years, evidence has accumulated that certain anatomic features, including a severe vessel tortuosity or aortic arch abnormalities, are associated with an increased periprocedural complication rate during CAS despite the use of cerebral protection devices.[4,5] Despite the small patient number, a technical failure rate of 11% in the cerebral protection group stresses the importance of excluding these patients from any future trial.

Irrespective of these limitations, we definitely concur with Barbato and colleagues that further randomized trials of unprotected versus protected CAS using DWI as an additional surrogate end point should be expedited. Ideally, these trials should include only patients with a symptomatic carotid stenosis, who are younger than 70 years of age.

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Reply

We read with interest the thoughtful letter to the editor of Kastrup et al and agree with most of the voiced comments, in particular the recommendation that additional investigation of the assumed salutory effects of distal protection filters should be undertaken. Our study was significantly underpowered to answer the question in a meaningful manner, and serves only to underscore our lack of understanding of the potential drawbacks of routine filter use during carotid artery stenting (CAS).

We are familiar with the authors' study referred to in the letter, showing findings quite different from ours in the frequency of diffusion-weighted magnetic resonance imaging lesions among patients treated with protected or unprotected CAS. We agree that age and symptomatic status explain many of the differences between the two reports, but the retrospective study methodology, as well as the multitude of filters used with different crossing profiles may have also influenced the findings. For example, their most commonly used filter crosses the lesion as a simple wire, which may be related to a lower incidence of noted microemboli. In addition, the use of filters as well as the performance of magnetic resonance imaging studies in their review did not follow specific indications, introducing a selection bias that further complicates the comparison of our two studies.

Although we agree with Kastrup's comments regarding the lack of benefit of asymptomatic octogenarians from interventional treatment in general and CAS in particular, care must be taken to avoid the use of our clinical outcomes in a very limited dataset to support or refute that contention. A larger review we previously published agrees with the opinions presented in the letter.[1] Our current manuscript, however, which includes only a fraction of our total experience, does not shed any additional light on the topic.

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Regarding "Aortic neck dilatation after endovascular abdominal aortic aneurysm repair: A word of caution"

Congratulations to Drs Diehm, Dick, Katzen, Schumidli, Kalka, and Baumgartner for their review article focusing on the phenomenon of neck dilation after endovascular abdominal aortic aneurysm repair.[1] However, this review did not include a study we recently conducted and published in the Journal of Endovascular Therapy.[2] This study concludes with valuable results because it